

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ENZO LIFE SCIENCES, INC.	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	<b>C.A. No. 12-275-LPS</b>
	)	
BECTON, DICKINSON AND COMPANY,	)	<b>JURY TRIAL DEMANDED</b>
BECTON DICKINSON DIAGNOSTICS INC.,	)	
and GENE OHM SCIENCES, INC.	)	
	)	
Defendant.	)	

**MOTION FOR LEAVE TO FILE  
FIRST AMENDED ANSWER TO AMENDED COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 15, Defendants Becton, Dickinson and Company, Becton, Dickinson Diagnostics Inc., and Geneohm Sciences, Inc. (collectively “BD”), hereby move this Court for an order granting it leave to file the First Amended Answer to Amended Complaint and Counterclaims (“Amended Answer”), attached hereto as Exhibit A. The Amended Answer includes a counterclaim for patent misuse and an affirmative defense and a declaratory judgment counterclaim that U.S Patent No. 7,064,197 (the ’197 patent) is unenforceable by reason of inequitable conduct. The Amended Answer also includes several other additions and deletions from the previously filed answer as evidenced in the attached redline, attached hereto as Exhibit B pursuant to D. Del. LR 15.1. Defendants make this motion to amend in good faith, not for any dilatory purpose, and prior to the deadline for amendments to pleadings ordered by this Court in its Amended Scheduling Order. (D.I. 41).

BD requests that the Court grant it leave so that it may assert a claim and affirmative defense of inequitable conduct with respect to the ’197 patent, as well as a claim of patent misuse. When BD filed its Answer to Amended Complaint and Counterclaims (D.I. 15), BD did

not have the proper factual basis to assert these claims and defenses. *See, e.g., Garr v. U.S. Healthcare, Inc.*, 22 F.3d 1274, 1278 (3d Cir. 1994) (“The signer’s signature on a pleading. . . certifies the signer has . . . made a reasonable inquiry into the contents of the pleading. . . and concluded that it is well grounded in fact and warranted in law. . .”). Since filing its original Answer to Amended Complaint and Counterclaims, BD has become aware of facts that substantiate the pleading of these claims and defenses.

## **I. ARGUMENT**

### **A. Legal Standards**

The Supreme Court has held that “leave to amend ‘shall be freely given when justice so requires.’” *Foman v. Davis*, 371 U.S. 178, 182 (1962) (quoting Fed. R. Civ. P. 15(a)). Additionally, “[t]he Third Circuit has adopted a liberal approach to the amendment of pleadings.” *Micron Tech., Inc. v. Rambus Inc.*, C.A. No. 00-792-JJF (D.I. 979) (D. Del. July 12, 2007) (citing *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990)). “Where the non-moving party will not suffer substantial or undue prejudice, denial of leave to amend must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment.” *Accenture Global Servs. GMBH v. Guidewire Software Inc.*, 631 F. Supp. 2d 504, 509 (D. Del. 2009) (Robinson, J.) (quoting *USX Corp. v. Barnhart*, 395 F.3d 161, 166 (3d Cir. 2004)) (internal quotation marks omitted). None of those circumstances exist in this case.

### **B. BD’s Motion Satisfies the Liberal Standard for Amendment**

BD’s motion for leave to amend meets the liberal standard for amendment. First, Enzo Life Sciences, Inc. (“Enzo”) will not suffer prejudice as a result of BD’s amendment. The parties remain in the midst of fact discovery, to be completed by June 17, 2014, no depositions

have yet been noticed or taken, and no trial date has been set. Enzo has known of the facts surrounding BD's defenses and counterclaims, and specifically, the alleged misrepresentations of the inventors of the '197 patent. Moreover, Enzo has had, and continues to have, every opportunity to gain the relevant discovery necessary from the inventors and other relevant persons. Second, BD does not move in bad faith or for dilatory tactics. BD has diligently investigated potential inequitable conduct and patent misuse claims and defenses, and in good faith alleges facts to support those claims and defenses. Third, BD timely moves to amend its answer within the deadline for the amendment of pleadings set for January 15, 2014. Finally, BD has sufficiently pled its inequitable conduct claims and defenses under Rule 9(b). The Amended Answer (¶¶116-164) provides the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009).

All of these factors point to allowance of the Amended Answer. *See Helios Software, LLC v. Awareness Techs., Inc.*, 2013 WL 6773658, at \*2 (D. Del. Dec. 19, 2013) (granting motion for leave to amend the answer to add counterclaim and defense of inequitable conduct almost a year after the deadline for amendments to pleadings); *Galderma Laboratories Inc. v. Amneal Pharmaceuticals, LLC*, 2013 WL 5461611, at \*1-2 (D. Del. Sept. 30, 2013) (granting motion to amend the answer to add affirmative defense and/or counterclaims of unenforceability due to inequitable conduct, unclean hands, and breach of contract).

BD contacted counsel for Enzo with respect to its position on BD's motion for leave to amend and provided its proposed amended answer but has not been informed as to its consent or opposition.

## II. CONCLUSION

BD therefore respectfully requests that this Court grant it leave to file the First Amended Answer to the Amended Complaint and Counterclaims, attached hereto as Exhibit A.

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Dated: January 15, 2014

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 15, 2014, I caused to be served true and correct copies of the foregoing document in the manner indicated below:

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